REMARKS

A. Status of the Claims

Claims 36-41, 43, 45 and 47-56 were pending at the time of the Action with claims 53-56 being withdrawn. Claim 45 has been amended for clarity. New claim 57 has been added. Support for claim 57 may be found in the specification at, for example, page 36, third paragraph. Claim 36 has been canceled and claim 40 re-written in independent form. New claims 58 and 59-61 have been added. Support for claims 59-61 may be found in claims 37 and 38. Claims 37-39 and 51-52 have also been canceled. Thus, claims 40-41, 43, 45, 47-50, and 53-61 are pending.

B. Objections to the Claims

Claims 45 and 51 are objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form. These objections are moot in view of the current claim amendments.

Claims 37 and 38 are objected to under 37 C.F.R. § 1.75(c) as being substantial duplicates. Applicants disagree. Although there is overlap in the sequences recited in claims 37 and 38, the sequences are not identical. However, to further clarify the differences between the subject matter of these claims, Applicants have canceled claims 37 and 38, and added new claims 59-61 directed to this subject matter.

C. The Rejections Under 35 U.S.C. §§ 102 and 103 Are Overcome

Claims 36, 39, 43, 45, 47, 48 and 51 are rejected under 35 U.S.C. § 102(e) as being anticipated by Breton *et al.* (U.S. Patent No. 6,562,958). Claims 36, 39, 43, 45, and 47-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Breton *et al.* in view of Meinke *et al.* (WO 02/059148). Claim 40 was not included in these rejections. Claim 36 has been canceled

and current claim 40 has been rewritten in independent form. Applicants, therefore, request the withdrawal of these rejections.

D. The Claims Are Enabled

The Action rejects claims 43, 45, and 47-51 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Action acknowledges that the specification is enabling for an immunogenic composition, but contends that the specification does not reasonably provide enablement for a vaccine composition. In particular, the Action argues that a vaccine is not enabled because the specification has not shown that the immunogenicity of SEQ ID NO:91 and fragments thereof correlates with protective immune response *in vivo*. Applicants traverse this rejection.

The specification provides an enabling disclosure for the vaccines encompassed by the current claims because the specification contains a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. Factors to be considered when determining whether a disclosure satisfies the enablement requirement include: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Current claim 43 is directed to a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen or fragment of claim 40 (claim 40 recites "An isolated hyperimmune serum-reactive antigen comprising an amino acid sequence consisting of SEQ ID NO:91 or a fragment of at least 8 contiguous amino acids of SEQ ID NO:91.") Current claim 57

is directed to a vaccine formulation comprising the pharmaceutical composition of claim 43. Thus, these claims are directed to a pharmaceutical composition and a vaccine formulation comprising a particular isolated hyperimmune serum-reactive antigen or fragment. In this regard, it is important to note the manner in which SEQ ID NO:91 was identified as a "hyperimmune serum-reactive." This antigen was identified from a screen with antibody preparations of individuals with ***an immunity or reactive immune system*** to *C. pneumoniae* (*see e.g.*., p. 13, para. 5 to p. 14, para. 3; Example 4 and Table 2). By using individual sera from individuals previously infected by *C. pneumoniae*, antigens with a proven capability of stimulating immunity were identified.

In addition, T cell epitopes were identified in the hyperimmune serum-reactive antigens (*see* Example 5 and Table 1). As stated in the specification, "The accuracy of the bioinformatic prediction methods for T cell epitopes are remarkable and thus offer a complementary method to the described antigen identification approach by bacterial surface display, which is based on the experimental identification on B cell epitopes." (Specification, p. 49). In other words, the identified hyperimmune serum-reactive antigens, such as SEQ ID NO: 91 are not only recognized by antibodies in human sera, but also contain predicted T cell epitopes (*see* Table 1).

The Action cites two references that discuss Chlamydia vaccines, Thorpe *et al.*, Puolakkainen *et al.*, Igietseme, *et al.* These references support the enablement of the present vaccine claims. First, these references show that protective immune responses against Chlamydia have been achieved with antigens identified through genomics and proteomics. In addition, these references demonstrate that *in vitro* and animal models of Chlamydia infection are known to those in the art. Thus, in view of the guidance in the specification regarding the evaluation of immune responses to the hyperimmune serum reactive antigens (*see e.g.*, Example

4 and p. 50) and the knowledge of those in the art, it would require no more than routine screening to make and use a vaccine formulation comprising an isolated hyperimmune serum-reactive antigen comprising an amino acid sequence consisting of SEQ ID NO:91 or a fragment of at least 8 contiguous amino acids of SEQ ID NO:91. Such screening would not constitute undue experimentation (*see In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Action points out that Igietseme *et al.* teaches that some Chlamydia subunit vaccines candidates that have demonstrated immunogenicity in vitro provided poor immunogenicity in vivo and only partial protective immunity. It is important to note, however, that Igietseme *et al.* teach that a product that provides a partial protective immunity is still considered a "vaccine" and even though it provides partial protective immunity it "would be an acceptable first generation product." (Igietseme *et al.*, page 140).

Applicants further note that "[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) The stage at which an invention in the pharmaceutical field becomes useful is well before it is ready to be administered to humans. *Id.*; *see also Ex parte Zavada*, Board of Patent Appeals and Interferences, Appeal No. 2001-1970 at page 10 ("First, we agree with Appellants that a therapeutic method need not be ready for clinical application in order to be enabled.") (non binding precedent). Accordingly, to the extent the Action may be requiring evidence of clinical efficacy in humans, this is not a requirement for patentability.

In view of the above, the present specification contains a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. Applicants, therefore, respectfully request the withdrawal of the rejection.

E. Conclusion

In view of the foregoing, Applicants submit that the claims are in condition for allowance and an early indication to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5654 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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